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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,712

04/09/2004

Tsuyoshi Sato

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08/24/2006

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EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/820,712	Applicant(s) SATO ET AL.	
	Examiner Hope A. Robinson	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 August 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action mailed April 18, 2006 on July 18, 2006, is acknowledged.

Claim Disposition

2. Claims 1-7 are pending. Claims 1-2 are under examination.

Withdrawn-Specification Objections

3. Previous objection to the specification are withdrawn by virtue of submission of an amendment.

Withdrawn-Sequence Compliance Objections

4. Previous objection to the specification are withdrawn by virtue of submission of an amendment.

Withdrawn-Objection to Claims

5. Previous objection to claims are withdrawn by virtue of submission of an amendment.

Withdrawn-Claim Rejections - 35 USC § 112

6. Previous rejections to claims under 35 U.S.C. 112 first paragraphs are withdrawn by virtue of submission of an amendment.

Withdrawn-Claim Rejections - 35 USC § 112

7. Previous rejection to claims under 35 U.S.C. 112 second is withdrawn by virtue of applicant's arguments presented on pages 9-10 of the amendment.

New Abstract Objection

8. The Abstract is objected to because of the following informalities:
The abstract is objected to because the sequence notation in line 4 is improper, see "SEQ ID NO;1" which should be "SEQ ID NO:1".

Correction is required.

New-Claim Objection

9. Claim 1 is objected to because of the following informalities:
For clarity and precision of claim language it is suggested that claim 1 is amended to read "... (g) serine, and wherein said isolated alkaline protease has alkaline protease activity".

Correction is required.

Withdrawn-Claim Rejections - 35 USC § 101

10. Previous rejection to claims under 35 U.S.C. 101 is withdrawn by virtue of submission of an amendment.

New-Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim recites added material, which is not supported by the original disclosure. Claim 2 recites "98.1% homology to SEQ ID NO:1" and the instant specification discloses the language of "95% or more homology" (see paragraph [0026] of the specification). Therefore, the specification lacks adequate written description.

Maintained-Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claim 1 remains rejected under 35 U.S.C. 102(e) as being anticipated by Hatada et al. (U.S. Patent No. 6,803,222, November 5, 2001), based on species (e) and (f).

Hatada et al. teach a protein sequence that is 97.5% identical to the claimed SEQ ID NO:1 (alkaline protease). Hatada et al. teach two of the point mutations recited in the claims, at position 226Tyr and at position 296Val. Therefore, the limitations of the claims are met by the reference.

Response to Arguments

13. The response filed on July 18, 2006 has been considered. The objections of record have been withdrawn, however, new objections have been instituted over the abstract and claims based on applicant's amendments. Note that the rejection of record under 35 U.S.C. 102 has been withdrawn in part pertaining to claim 2. As the amended language obviates the prior art of record the rejection under 35 U.S.C. 102 over claim 2 is withdrawn, however, will be reinstituted when the new matter is removed from the

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claim. The cited reference by Hatada et al. remains relevant over the instant claim 1. Applicant on page 8 of the response states that sequence of Hatada et al. does not meet the limitations of claim 1 which requires SEQ ID NO:1. This argument is not persuasive. The Hatada et al. reference teaches a sequence that comprises 434 residues and the instant SEQ ID NO:1 comprises 434 residues. The Hatada et al. reference teaches two of the point mutations recited in the claim as stated above, however, has additional mutations which differ from the other 5 mutations recited in claim 1. Note that claim 1 is directed to "one or more residues" selected from the specific point mutations and the claim recites the open language of "having" which is equivalent to comprising, thus is not limited to the 7 positions recited in the claim. The disclosed 97.5% sequence identity to SEQ ID NO:1 is over the full-length sequence and a result of the additional mutations, which are encompassed in the open language recited in the claim (several of which are conservative substitutions). Thus, the rejection remains.

Note that a new ground of rejections has been instituted under 35 U.S.C. 112, first paragraph, written description for the reasons stated above, based on amendments made to the claim.

Conclusion

14. No claims are allowable.

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15. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner

HOPE ROBINSON
PATENT EXAMINER

8/16/06
